MAR 0 1 2007

K063815

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Esophagus Bougie Applicator.

- **Submitter:** Varian Medical Systems
  3100 Hansen Way M/S E-110
  Palo Alto, CA 94304-1129
  Contact Name: Ms. Vy Tran
  Phone: (650) 424-5731
  Fax: (650) 842-5040
  Email: vy.tran@varian.com
  Date summary was prepared: December 18, 2006

- **Name of the Device:** **Varian Esophagus Bougie Applicator**
  Trade/Proprietary Name: Varian Esophagus Bougie Applicator
  Common or Usual Name: Varian Esophagus Bougie Applicator
  Classification Name: System, Applicator, Radionuclide, Remote-Controlled
  21 CFR §892.5700
  Class II
  Product Code: JAQ

- **Predicate Devices** to claim substantial equivalence:
  K891131 & K983436

- **Description of the Device:** The Varian Esophagus Bougie is an HDR applicator designed to facilitate delivery of radiation to the Esophagus and has been modified to work with Varian afterloaders. The product can be steam sterilized up to 20 times and has a maximum implantation time of 24 hours. The device does not contain any electronics or software.

  A high activity radioactive source is placed within the applicator which has previously been placed for a specified clinical purpose in a patient.

  The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into the applicator within the patient.

  The length of time and position that the High Dose Rate source spends within the applicator is controlled in accordance with an Irradiation Treatment Prescription.

- **Intended Use Statement**: The Varian Esophagus Bougie is an applicator used to facilitate delivery of a prescription of radiation to the esophagus when used in conjunction with a Varian high dose rate afterloader.

- **Summary of the Technological Characteristics:** The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate device. This chart is located in Tab 8 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAR 0 1 2007

Ms. Vy Tran
Corporate Director Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way
PALTO CA 94304-1038

Re: K063815
Trade/Device Name: Esophagus Bougie Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: December 18, 2006
Received: December 22, 2006

Dear Ms. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Varian Esophagus Bougie Applicator - Statement of Intended Use

510(k) Number (if known): K063815

Device Name: Varian Esophagus Bougie Applicator

Intended Use Statement: The Varian Esophagus Bougie is an applicator used to facilitate delivery of a prescription of radiation to the esophagus when used in conjunction with a Varian high dose rate afterloader.

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063815

Prescription Use ✓